

Remarks

Claims 1-15 were pending in the subject application. By this Amendment, the applicants have amended claims 1 and 3 and claims 5-14 remain withdrawn. Support for the amendments to the claims can be found throughout the subject specification as originally filed, and specifically at, for example, page 3, first full paragraph where the role of the claimed polynucleotide sequence in lymphoid development is described. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-4 and 15 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, the applicants acknowledge that the subject matter of claims 5-14 are withdrawn as being directed to non-elected inventions. By this Amendment, the non-elected subject matter has been canceled.

The amendments set forth herein have been made to lend greater clarity to the claimed subject matter. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1-4 and 15 have been rejected under 35 U.S.C. §112, first paragraph. The applicants have amended claim 1 to more clearly define the claimed subject matter. Specifically, claim 1 has been amended to clarify that the artificial chromosomes of the subject invention comprise a region that is not only between C $\delta$  and C $\gamma$ 3, but also regulates immunoglobulin gene activation during lymphoid development. The subject application not only provides examples of such sequences as well as assays for readily identifying this activity. Given the detailed guidance provided in the subject application, a person skilled in the art could readily make and use the invention without the need for undue experimentation. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 1-4 and 15 have been rejected under 35 U.S.C. §112, second paragraph. By this Amendment, the applicants have amended the claims to address the issues raised by the examiner. Specifically, as noted above, claim 1 has been amended to lend greater clarity by explicitly reciting a distinctive functional characteristic of the claimed sequences. Additionally, claim 3 has been amended in accordance with the Examiner's helpful suggestion to clarify that the claimed sequences

encode a transcription binding factor. In view of the amendments to the claims, the metes and bounds of the claimed subject matter would be readily apparent to a person skilled in the art. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claims 1-3 have been rejected under 35 U.S.C. §102(b) as being anticipated by Turgeon *et al.* (JMB, January 21, 2000, Vol. 295(3), pages 489-504). Also, claims 1, 2 and 4 have been rejected under 35 U.S.C. §102(b) as being anticipated by Larionov *et al.* (PNAS, 1996, Vol. 93, pages 13925-13930). The applicants respectfully traverse this grounds for rejection because the cited references do not disclose, or even suggest, the applicants' unique and advantageous artificial chromosomes comprising the specific nucleotide sequences having the recited functionality.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The cited references clearly do not explicitly disclose artificial chromosomes having nucleotide sequences from between C $\delta$  and C $\gamma$ 3 of the human IgH locus that are involved in regulating gene expression in lymphoid development. Nor can it be said that the cited references "inherently" disclose the claimed subject matter.

Under the Patent Laws, a prior art rejection based on inherency is proper only if the prior art necessarily resulted in the claimed subject matter. *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

The doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation....A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ2d 1001, 1032-33 (E.D. KY 1988).

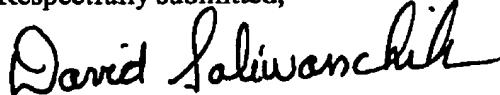
There is no reason to believe that the cited references disclose constructs meeting the limitations of the current applicants' claims and it is definitely not a certainty, as required under the Patent Laws. Therefore, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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